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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,232	05/02/2001	Ning Huang	0665-0018.30	5945

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,232

Applicant(s)

HUANG ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/12/03, 5/2/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/10/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed 9/20/2004 has been entered.
2. Claims 18 and 23-24 are pending and said claims including SEQ ID NO:26 and 35 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Indefiniteness

5. Claims 18, and 23-24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Rejection includes dependent claims.

Claim 18 remains indefinite in the recitation "Gt1". The sole designation of a promoter sequence by "Gt1", is arbitrary and creates ambiguity in the claims. For example, amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different promoter or amino acid sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/20/2004. Applicant's arguments filed 9/20/2004 have been fully considered but they are not persuasive.

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Applicants contend that the term Gt1 is accepted in the art to refer to the monocot endosperm-specific glutelin gene as described in Okita et al (J Biol Chem., 264(21):12573-81, 1989) (page 3, item III).

The Office contends that Applicants' claim is directed to any monocot glutelin seed-specific promoter while the cited art is directed to a rice glutelin seed-specific promoter. Applicants have not shown that the rice glutelin seed-specific promoter is representative of all glutelin seed-specific promoters from all monocot plants.

If
Gt1 is
art-
recognized,
drop this.

Claim 18 is indefinite for including parentheses around "Gt1" and "Reb". It is not clear what the intended parenthetical meaning of "(Gt1)" and "(Reb)" ^{whether} ~~is~~ are intended to be claim limitations or examples. It is suggested that the parentheses be deleted to clarify ~~that~~ these recitations are intended to be claim limitations.

Written Description

6. Claims 18 and 23-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/20/2004. Applicant's arguments filed 9/20/2004 have been fully considered but they are not persuasive.

Applicants contend that determination of the response sequence for Reb UAS by band shift assay is described in the specification on page 19, lines 10-13. Applicants also contend that determination of Reb binding sites for determining the response sequence is described in detail in Nakase et al (Plant Molecular Biology, 33:513-522, 1997) (page 6, item 2.1). Applicants

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contend that based on the guidance in the specification at the time of filing, one of skill in the art would reasonably conclude that Applicants were in possession of “determining the native response sequence for the Reb transcription factor” (page 7, top paragraph).

The Office contends that Applicants have not fulfilled the written description requirement for native response sequences for the Reb transcription factor. Supplying methods for making the determination does not constitute being in possession of the claimed invention. Applicants’ invention is a method of making an endosperm-specific glutelin seed-specific promoter responsive to a rice basic leucine-zipper protein transcription factor to which it is not normally responsive. Applicants have not described a representative number of Reb response sequences or Applicants have not shown that Reb response sequences are known in the art. Without either of this information, Applicant is not in possession of the claimed invention.

Applicants contend that the sequences for the native monocot Gt1 seed-specific promoters are obtainable in the literature or in public databases as evidenced by Accession No. AY387493 for *Zea mays*. Applicants contend that Gt1 promoters may be isolated from other extracts, e.g., wheat, oat, or the like using conventional hybridization techniques (page 7, 4th paragraph).

The office contends that Applicants have not fulfilled the written description requirement for claims drawn to any monocot endosperm-specific glutelin (Gt1) seed-specific promoter. Applicants have only disclosed one sequence of SEQ ID NO:26. The Accession No. AY387493 (Liu et al, 2003, NCBI Accession number AY387493) is for a *Zea mays* putative glutathione transporter (Gt1) and not for an endosperm-specific glutelin (Gt1) seed-specific promoter. Therefore, monocot endosperm-specific glutelin (Gt1) seed-specific promoters are not known in

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the art. Applicants are only in possession of a Gt1 promoter of SEQ ID NO:26, and not the genus of monocot endosperm-specific glutelin (Gt1) seed-specific promoters.

Applicants contend that methods of determining whether the Gt1 seed specific promoter responds to the Reb transcription factor are listed in the specification. Applicants contend that they are in possession of "providing a heterologous nucleic acid construct comprising a native monocot Gt1 seed-specific promoter that does not respond to the Reb transcription factor" at the time of filing the application. Applicants also discuss "inserting the response sequence into the Gt1 promoter resulting a modified Gt1 promoter which is effective to bind the Reb transcription factor" (page 7, bottom paragraph and page 8, lines 10-6).

The Office contends that Applicants are arguing items not presented in the written description rejection set forth in the office action mailed 4/20/2004.

Applicants do not understand how statements presented in the written description rejection are relevant to the presently claimed invention. Applicants contend that the claimed invention is a method of making a modified endosperm-specific (Gt1) seed-specific promoter responsive to a rice basic leucine-zipper protein (Reb) transcription factor. Applicants contend ample guidance for each of the claimed steps is given (paragraph bridging pages 8 and 9).

The Office contends that Applicants are not in possession of the genus of monocot endosperm-specific glutelin (Gt1) seed-specific promoter or any native response sequences for the Reb transcription factor. Presenting methods of isolating the claimed components that are to be used in the claimed method does not constitute being in possession of the claimed components. Given the lack of description of the necessary elements essential for the monocot endosperm-specific (Gt1) seed-specific promoter, Reb transcription factors, or upstream

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activation sequences to which any Reb transcription factor would bind, it remains unclear what features identify any of these sequences. Since the genus of monocot endosperm-specific (Gt1) seed-specific promoters, Reb transcription factors, and upstream activation sequences to which a Reb transcription factor binds has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Scope of Enablement

7. Claims 18 and 23-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making a modified endosperm rice glutelin 1, Gt1, promoter of SEQ ID NO:26 in which a 98 bp *Oryza sativa* bZIP, Reb, upstream activation sequence (UAS) fragment containing three copies of GCCACGT(C/A)AG whose sequence is set forth in SEQ ID NO:36 was inserted at position -630 bp distal to the TATA box of said Gt1 promoter (page 31, lines 13-19), operably linked to any encoding nucleic acid sequence and co-transformed with a nucleic acid sequence of SEQ ID NO:35 which encodes a Reb transcription factor, to increase expression of said encoding nucleic acid sequence compared to a plant not transformed with the Reb transcription factor (page 31, lines 20-25), does not reasonably provide enablement for claims broadly drawn to a method of making any Gt1 seed-specific promoter responsive to any Reb transcription factor comprising determining the native response sequence for any Reb transcription factor, and inserting said responsive sequence into any Gt1 promoter in any location. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the

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Official action mailed 4/20/2004. Applicant's arguments filed 9/20/2004 have been fully considered but they are not persuasive.

Applicants contend that the specification teaches how to determine the native response sequence for the Reb transcription factor by band shift assay and also Nakase et al disclose said method (page 11, 1st and 2nd paragraphs).

The Office contends that undue trial and error experimentation would be required by one of skill in the art to identify response sequences for the rice basic leucine-zipper protein, Reb, transcription factor, given all the potential sequences that must be tested and given that Applicant has not taught essential elements of the response sequence for the rice basic leucine-zipper protein, Reb transcription factor.

Applicants contend that they have provided the native Gt1 sequence for Oryza sativa as SEQ ID NO:26 and that native monocot Gt1 seed-specific promoters are additionally obtainable in the literature or in public databases as evidenced by Accession No. AY387493 for Zea mays.

The Office contends that Applicants' claims are drawn to any monocot Gt1 seed-specific promoter but Applicants have only provided one sequence for the rice Gt1 promoter of SEQ ID NO:26. Applicants have not disclosed sequences that can be used to identify or isolate any monocot Gt1 seed-specific promoter. In addition, the Accession No. AY387493 is for a Zea mays putative glutathione transporter (Gt1) which is not the same as an endosperm-specific glutelin, Gt1, seed-specific promoter. Given the lack of disclosure of essential elements for any monocot Gt1 seed-specific promoter, it would require undue trial and error experimentation to identify and isolate said promoter by one skilled in the art.

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Applicants contend that they do not understand the relevance of the Examiner's assertion that Applicants have not taught any other UAS elements to which any Reb transcription factor will bind. Applicants contend that they are claiming a method and that they teach techniques that would be used to identify components of the claimed method, e.g., using a band-shift assay (page 13, 3rd paragraph).

The Office contends that it would require undue trial and error experimentation by one skilled in the art to practice the claimed method given the lack of specific information regarding response sequences for a rice Reb transcription factor and given the lack of sequence information for the genus of monocot Gt1 seed specific promoters. Disclosing methods that can be used to isolate specific DNA sequences does not full the enablement requirement, given the multitude of sequences that have to be tested, taking into account the state-of-the-art and the level of unpredictability as disclosed in the office action dated 4/20/2004.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
December 3, 2004

Phuong T. Bui 12/7/04

**PHUONG T. BUI
PRIMARY EXAMINER**